



PATENT
Attorney Docket No. MEE-002

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S): Miller et al.
SERIAL NO.: 09/780,142 GROUP NO.: 1644
FILING DATE: February 9, 2001 EXAMINER: Phuong N. Huynh
TITLE: Methods and Compositions for Treating Conditions of the Eye

Commissioner for Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☐ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☒ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☒ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

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- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

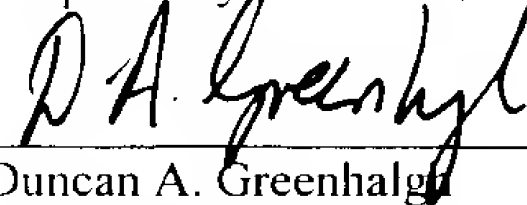
As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: April 18, 2003
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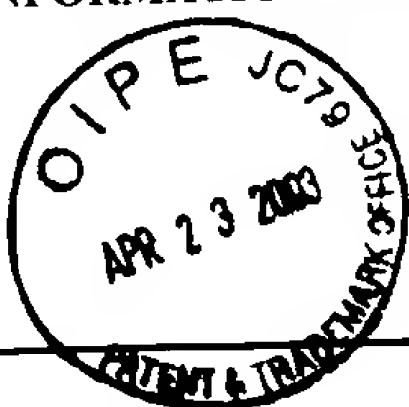
Respectfully submitted,



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FORM PTO - 1449

INFORMATION DISCLOSURE STATEMENT



ATTORNEY DOCKET NO.: MEE-002

APPLICANTS: Miller *et al.*

SERIAL NO.: 09/780,142

FILING DATE: February 9, 2001

EXAMINER: Huynh, P. GROUP: 1644

COPY

U.S. PATENT DOCUMENTS

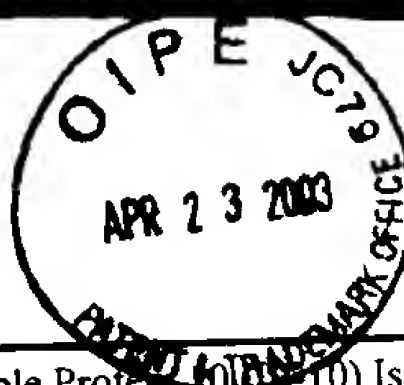
EXAM. INIT.		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	A1	5,707,986	1/13/98	Miller et al.	514	185	
	A2	5,733,876	3/31/98	O'Reilly et al.	514	12	
	A3	5,798,349	8/25/98	Levy et al.	514	185	
	A4	5,854,205	12/29/98	O'Reilly et al.	512	2	
	A5	6,117,862	9/12/00	Margaron et al.	514	185	
	A6	6,180,402	1/30/01	Granville et al.	435	375	
	A7	6,225,303	5/1/01	Miller et al.	514	185	

FOREIGN PATENT DOCUMENTS

EXAM. INIT.		DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	WO 95 24930 A	09/21/95						
	B2	WO 97 33619 A	09/18/97						
	B3	WO 97 45450 A	12/04/97						
	B4	WO 98 25648 A	06/18/98						
	B5	WO 99 03503 A	01/28/99						
	B6	WO 00 51638	09/08/00						
	B7	WO 01 51087 A	07/19/01						

OTHER ART, JOURNAL ARTICLES, ETC.

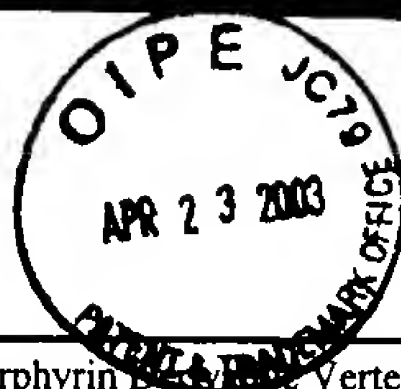
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C1	Adamis et al. "Inhibition of Vascular Endothelial Growth Factor Prevents Retinal Ischemia - Associated Iris Neovascularization in a Nonhuman Primate" (1996) <u>Arch Ophthalmol</u> , Vol. 114, pp: 66-71.
	C2	Ahmad et al "Photodynamic Therapy Results in Induction of WAF1/C1P1/P21 Leading to Cell Cycle Arrest and Apoptosis" (1998) <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 95, pp: 6977 - 6982.
	C3	Allen et al. "Photodynamic Therapy: Tumor Targeting with Adenoviral Proteins" (1999) <u>Photochemistry and Photobiology</u> , Vol.70, No. 4, pp: 512-523.
	C4	Akhlynina et al. "Insulin-mediated Intracellular Targeting Enhances the Photodynamic Activity of Chlorin e ₆ " (1995) <u>Cancer Research</u> , Vol 55, pp1014-1019.



C5	Arenberg et al. "Interferon- γ -inducible Protein (IP-10) Is an Angiostatic Factor That Inhibits Human Non-small Cell Lung Cancer (NSCLC) Tumorigenesis and Spontaneous Metastases" (1996) <u>J. Exp. Med.</u> Vol. 184, pp 981-992.
C6	Ball et al. "A Comparative Study of the Cellular Uptake and Photodynamic Efficacy of Three Novel Zinc Phthalocyanines of Differing Charge" (1999) <u>Photochemistry and Photobiology</u> , Vol. 69, No.3, pp: 390-396.
C7	Berg, K. and Moan, J. "Lysosomes and Microtubules as Targets for Photochemotherapy of Cancer" (1997) <u>Photochemistry and Photobiology</u> , Vol. 65, No. 3, pp: 403-409.
C8	Biolo et al. "Effect of Photosensitizer Delivery System and Irradiation Parameters on the Efficiency of Photodynamic Therapy of B16 Pigmented Melanoma in Mice" (1996) <u>Photochemistry and Photobiology</u> , Vol. 63, No. 2, pp: 224-228.
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C11	Bressler, et al. "Age-related Macular Degeneration" (1998) <u>Survey of Ophthalmology</u> , Vol. 32, No. 6, pp: 375-413.
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C13	Brooks et al. "Requirement of Vascular Integrin $\alpha_v\beta_3$ for Angiogenesis" (1994) <u>Science</u> , Vol. 264, pp: 569-571.
C14	Ciardiello et al. "Antitumor Activity of Combined Blockade of Epidermal Growth Factor Receptor and Protein Kinase A" (1996) <u>J. Natl. Can. Inst.</u> , Vol. 88, No. 23, pp: 1770-76.
C15	Ciulla T A et al. "Changing Therapeutic Paradigms for Exudative Age-related Macular Degeneration: Antiangiogenic Agents and Photodynamic Therapy" (1999) <u>Expert Opinion on Investigational Drugs</u> , Ashley Publications LTD, Vol. 8, No. 12, pp: 2173-2182.
C16	D'Amato et al. "Thalidomide is an Inhibitor of Angiogenesis" (1994) <u>Proc. Natl. Acad. Sci. USA</u> , Vol. 91, pp: 4082-4085.
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C21	Ferrario et al. "Antiangiogenic Treatment Enhances Photodynamic Therapy Responsiveness in a Mouse Mammary Carcinoma" (2000) <u>Cancer Research</u> , Vol. 60, No. 15, pp: 4066-4069.
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C23	Folkman, J. "Angiogenesis in Cancer, Vascular, Rheumatoid and Other Disease" (1995) <u>Nature Medicine</u> , Vol. 1, pp: 27-31.
C24	Friedlander et al. "Definition of Two Angiogenic Pathways by Distinct α_v Integrins" (1995) <u>Science</u> , Vol. 270, pp: 1500-1502.



C25	Friedlander et al. "Involvement of Integrins $\alpha_v\beta_3$ and $\alpha_v\beta_5$ in Ocular Neovascular Diseases" (1996) <u>Pro. Natl. Acad. Sci. USA</u> , Vol. 93, pp. 9764-9769.
C26	Granville et al. "Overexpression of Bcl-X _L Prevents Caspase-3-mediated Activation of DNA Fragmentation Factor (DFF) Produced by Treatment with the Photochemotherapeutic Agent BPD-MA" (1998) <u>FEBS Letters</u> , Vol. 422, pp: 151-154.
C27	Granville et al. "Rapid cytochrome c Release, Activation of Caspases 3, 6, 7 and 8 Followed by Bap31 Cleavage in HeLa cells Treated with Photodynamic Therapy" (1998) <u>FEBS Letters</u> , Vol. 437, pp: 5-10.
C28	Gupta et al. "Involvement of Nitric Oxide During Phthalocyanine (Pc4) Photodynamic Therapy-Mediated Apoptosis" (1998) <u>Cancer Research</u> , Vol. 58, pp: 1785-1788.
C29	Guyer et al. "Subfoveal Choroidal Neovascular Membranes in Age-Related Macular Degeneration" (1986) <u>Arch Ophthalmol</u> , Vol. 104, pp: 702-705.
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C31	Hanahan, D. and Folkman, J. "Patterns and Emerging Mechanisms of the Angiogenic Switch during Tumorigenesis" (1996) <u>Cell</u> , Vol. 86, pp: 353-364.
C32	He et al. "Photodynamic Therapy with Photofrin II Induces Programmed Cell Death in Carcinoma Cell Lines" (1994) <u>Photochemistry and Photobiology</u> , Vol. 59, No. 4, pp: 468-473.
C33	He et al. "The Induction of Partial Resistance to Photodynamic Therapy by the Protooncogene BCL-2" (1996) <u>Photochemistry and Photobiology</u> , Vol. 64, No. 5, pp: 845-852.
C34	He et al. "Variation in Photodynamic Efficacy during the Cellular Uptake of Two Phthalocyanine Photosensitizers" (1998) <u>Photochemistry and Photobiology</u> , Vol. 67, No. 6, pp: 720-728.
C35	Hockenbery et al. "Bcl-2 Functions in an Antioxidant Pathway to Prevent Apoptosis" (1993) <u>Cell</u> , Vol. 75, pp 241-251.
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C46	Kramer, et al. "Liposomal Benzoporphyrin Derivative Verteporfin Photodynamic Therapy" (1996) <u>Ophthalmology</u> , Vol. 103, No. 3, pp: 427-438.
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C50	Mauceri et al. "Combined effects of Angiostatin and Ionizing Radiation in Antitumour Therapy" (1998) <u>Nature</u> , Vol. 394, pp: 287-291.
C51	Miller et al. "Alternative Treatments of Neovascular Age-Related Macular Degeneration" (1999) Chapter 139, pp 2014-2027.
C52	Miller JW et al. "Photodynamic Therapy of Experimental Choroidal Neovascularization Using Lipoprotein-deliver Benzoporphyrin" (1995) <u>Archives of Ophthalmology</u> , Vol. 113, No. 6, pp: 810-818.
C53	Mori et al. "Photodynamic Therapy for Experimental Tumors Using ATX-S10(Na), a Hydrophilic Chlorin Photosensitizer, and Diode Laser." (2000) <u>Jpn. J. Cancer</u> , Vol. 91, No. 7, pp: 753-9.
C54	Moser et al. "Angiostatin binds ATP Synthase on the Surface of Human Endothelial Cells" (1999) <u>Proc. Natl Acad. Sci USA</u> , Vol. 96, pp: 2811-2816.
C55	Mosmann, T. "Rapid Colorimetric Assay for Cellular Growth and Survival: Application to Proliferation and Cytotoxicity Assays" (1983) <u>Journal of Immunological Methods</u> , Vol. 65, pp: 55-63.
C56	Netland et al. "In situ Labelling of Vascular Endothelium with Fluorescent Acetylated Low Density Lipoprotein" (1985) <u>Histochem J.</u> , Vol. 17, pp: 1309-1320.
C57	Nicholson, D. and Thornberry, N. "Capases: Killer Proteases" (1997) <u>TIBS</u> , Vol. 22, pp: 299-306.
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C62	O'Reilly et al. "Angiostatin Induces And Sustains Dormancy Of Human Primary Tumors In Mice" (1996) <u>Nature Medicine</u> , Vol. 2, No. 6, pp: 689-692.
C63	O'Reilly et al. "Angiostatin: A Novel Angiogenesis Inhibitor That Mediates the Suppression of Metastases by a Lewis Lung Carcinoma" (1994) <u>Cell</u> , pp: 315-328.
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C65	Pidgeon & Colles et al. "Recent Developments In Tunable Lasers For Spectroscopy" (1979) <u>Nature</u> , Vol. 279, pp: 377-381.
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C69	Ryan "Subretinal Neovascularization: Natural History of an Experimental Model" (1982) <u>Arch Ophthalmol.</u> Vol. 100, pp: 1804-1809.
C70	Schmidt-Erfurth, U. et al. "Photodynamic therapy in Ocular Vascular Disease" (1998) <u>Laser Phys.</u> , Vol. 8, No. 1, pp: 191-198.
C71	Senior, K. "Ageing eyes retain their mystery." (1999) <u>The Lancet</u> Vol. 353, pp: 818.
C72	Separovic et al "Association of Ceramide Accumulation with Photodynamic Treatment-Induced Cell Death" (1998) <u>Photochemistry and Photobiology</u> , Vol. 68, No. 1, pp: 101-109.
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C74	Stellmach et al. "Prevention of Ischemia-Induced Retinopathy by the Natural Ocular Antiangiogenic Agent Pigment Epithelium-Derived Factor" (2000) <u>Proc. Natl. Acad. Sci.</u> pp: 1-5.
C75	Tolentino et al. "Vascular Endothelial Growth Factor Is Sufficient to Produce Iris Neovascularization and Neovascular Glaucoma in a Nonhuman Primate" (1996) <u>Arch Ophthalmol.</u> Vol. 114, pp: 964-969.
C76	Varnes et al. "Photodynamic Therapy-Induced Apoptosis in Lymphoma Cells: Translocation of Cytochrome c Causes Inhibition of Respiration as Well as Caspase Activation" (1999) <u>Biochem. & Biophys. Res. Com.</u> , Vol. 255, pp: 673-679.
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C80	Vrouenraets, et al. "Targeting of a Hydrophilic Photosensitizer by Use of Internalizing Monoclonal Antibodies: A New Possibility for Use in Photodynamic Therapy" (2000) <u>Int. J. Cancer</u> , Vol. 88, pp: 108-114.
C81	Weishaupt et al. "Identification of Singlet Oxygen as the Cytotoxic Agent in Photo-inactivation of a Murine Tumor" (1976) <u>Can. Res.</u> , Vol. 36, pp: 2326-2329.
C82	West et al. "A Comparson Of The Sensitivity To Photodynamic Treatment Of Endothelial And Tumour Cells In Different Proliferative States" (1990) <u>Int. J. Radiat. Biol.</u> , Vol. 58, No. 1, pp: 145-156.
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INFORMATION DISCLOSURE STATEMENT
US 09/780,142



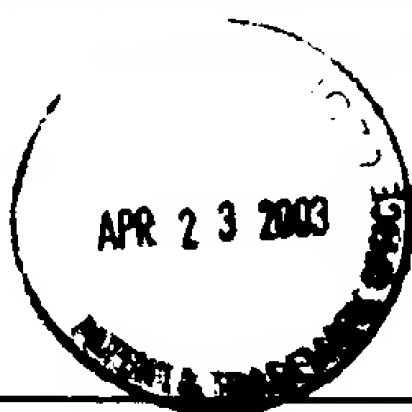
Sheet 6 of 6

	C86	International Preliminary Examination Report for PCT/US01/04231 dated May 12, 2001 (5 pages).
EXAMINER		DATE CONSIDERED

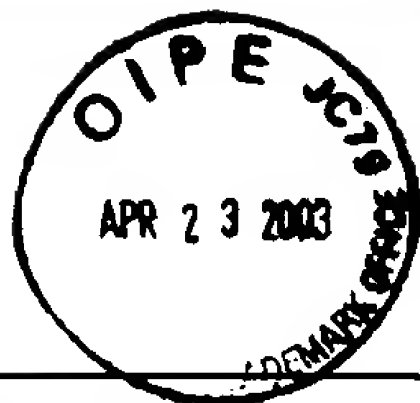
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FORM PTO - 1449 SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT				ATTORNEY DOCKET NO.: MEE-002 APPLICANT(S): Miller et al. SERIAL NO.: 09/780,142 FILING DATE: February 9, 2001 GROUP: 1644				
U.S. PATENT DOCUMENTS								
EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE		
	A8	6,331,523	12/18/01	Kljavin et al.	514	12		
FOREIGN PATENT DOCUMENTS								
EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
OTHER ART, JOURNAL ARTICLES, ETC.								
EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	C87	Abels et al. "Targeting of the Tumor Microcirculation by Photodynamic Therapy with a Synthetic Porphycene" <u>J. Photochem. Photobiol. B.</u> (1997) 40(3): 305-12 Abstract.						
	C88	Binétruy-Tournaire et al. "Identification of a Peptide Blocking Vascular Endothelial Growth Factor (VEGF)-mediated Angiogenesis" <u>EMBO Journal</u> (2000) 19(7): 1525-1533.						
	C89	Brokx et al. "Designing Peptide-based Scaffolds as Drug Delivery Vehicles" <u>J. Control Release</u> (2002) 78(1-3): 115-23 Abstract.						
	C90	Clauss et al. "Vascular Permeability Factor: A Tumor-derived Polypeptide that Induces Endothelial Cell and Monocyte Procoagulant Activity, and Promotes Monocyte Migration" <u>J. Exp. Med.</u> (1990) 172: 1535-1545.						
	C91	Dolmans et al. "Targeting Tumor Vasculature and Cancer Cells in Orthotopic Breast Tumor by Fractionated Photosensitizer Dosing Photodynamic Therapy" <u>Cancer Res.</u> (2002) 62(15): 4289-94 Abstract.						
	C92	Gruber et al. "Angiogenic Factors Stimulate Mast-Cell Migration" <u>Blood</u> (1995) 86(7): 2488-2493.						
	C93	Guerrin et al. "Vasculotropin/Vascular Endothelial Growth Factor is an Autocrine Growth Factor for Human Retinal Pigment Epithelial Cells Cultured in Vitro" <u>J. Cell. Phys.</u> (1995) 164: 385-394.						
	C94	Hackett et al. "Receptors for VEGF (flt-1 and flk-1) are Expressed in Nonvascular Cells in the Eye" <u>Invest. Ophthalm. & Vis. Sci.</u> (1996) 37(3) Abstract.						
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EXAMINER				DATE CONSIDERED				



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